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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/537,859	03/28/2000	Paul Proost	49673	5520

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EXAMINER

MERTZ, PREMA MARIA

ART UNIT PAPER NUMBER

1646

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/537,859	<b>Applicant(s)</b> PROOST ET AL.	
	<b>Examiner</b> Prema M Mertz	<b>Art Unit</b> 1646	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 June 2004, 3 October 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24-27 and 31-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-27, 31-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. Claims 1-23, 28-30 have been canceled previously. Claims 24-27, amended claims 31-34 (6/17/04) are under consideration.
2. Receipt of applicant's arguments and amendments filed on 6/17/04, 10/3/03 is acknowledged.
3. Applicant's arguments filed on 6/17/04, 10/3/03, have been fully considered but were persuasive in part. The issues remaining are stated below.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Applicants formal drawings submitted on 10/3/03 are acknowledged and accepted by the Examiner.
6. Applicants compliance with the sequence rules and amendment of claim 31 to reflect SEQ ID NO:2 is acknowledged.

***Claim Rejections - 35 USC § 103***

7. Claims 24-27, 31-34 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Van Damme et al. (J. Exp. Med. 1992, 176:59-65, IDS #AM) in view of Gong et al. (J. Exp. Med. 1995, 181:631-640, IDS AP), and further in view of Van Coillie et al. (Biochem Biophys. Res. Com. March 1997, 231:726-730, IDS #AS).

This rejection is maintained for reasons of record set forth at pages 4-6 of the previous Office action (3/31/03).

Applicants argue that the Examiner provides no support for any belief that the smallest truncations shown by Gong showed the least displacement and therefore the least amount of inhibition in assays used to evaluate efficacy. Furthermore, Applicants

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argue that the Examiner points to no teaching in Van Damme or Van Coille that would lead one of skill in the art to apply the teachings of Rollins to obtain the specific truncations claimed in the instant invention. However, contrary to Applicants arguments, the references are presumed to be valid with respect to the amino-terminal truncations of MCP-2, because the teachings with respect to MCP-1 would be expected to be applicable to MCP-2 since MCP-2 is a structural and functional equivalent of MCP-1. The ordinary artisan at the time the invention was made would have been motivated to apply the production and screening of progressive amino terminal deletions approach used by Gong et al. to develop MCP-I antagonists, to also develop antagonistic amino terminal truncations of MCP-2. Since both MCP-2 and MCP-I recruit monocytes which are important in a variety of inflammatory conditions; the ordinary artisan at the time the invention was made would have been motivated to produce and screen multiple amino-terminal truncations of MCP-2 in order to identify an antagonist of MCP-2 that could be substituted or combined with antagonists of MCP-I to better inhibit monocyte recruitment in those inflammatory conditions. In addition, Applicants arguments are non-persuasive because if Gong et al taught all the limitations of the instant invention, this rejection would be a 35 U.S.C. § 102(b) rejection rather than a 35 U.S.C. § 103 rejection.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

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Applicants arguments would be more persuasive if the claims were amended to recite “an isolated amino-terminally truncated MCP-2 polypeptide consisting of residues....of SEQ ID NO:2”.

8. Claims 24-27, 31-34 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rollins et al. (U.S. Pat. No. 5,739,103, of record) in view of Van Damme et al. (J. Exp. Med., 1992, 176:59-65, IDS #AM) and further in view of Van Coillie et al. (Biochem Biophys. Res. Com., March 1997, 231:726-730, IDS #AS).

This rejection is maintained for reasons of record set forth at pages 6-7 of the previous Office action (3/31/03).

Applicants argue that the Examiner points to no teaching in Van Damme or Van Coillie that would lead one of skill in the art to apply the teachings of Rollins to obtain the specific truncations claimed herein. Furthermore, Applicants argue that the “obvious-to-try” is an incorrect standard where the claimed result, the generation of compounds and pharmaceutical compositions with chemokine antagonistic activity. However, contrary to Applicants arguments, Rollins et al. provide clear guidance to delete amino acids from position 1 to position 10 of the amino terminus of the chemokines taught, including MCP-2. Rollins et al. teach a small genus of amino terminal truncations of chemokines including MCP-2, but does not reduce to practice or explicitly list the members of this genus. The ordinary artisan would have been motivated to produce the instantly recited truncations of MCP-2 as part of the routine optimization and screening of the small genus of truncations taught by Rollins et al. The ordinary artisan at the time the invention was made would have been motivated to make the instantly recited truncations of MCP-2 and formulate them in pharmaceutically

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acceptable carriers in order to compare the relative potency of each member of the small genus taught by Rollins et al. as antagonists in models of inflammation; and thereby identify the most potent antagonist. Both Rollins et al. and Van Damme et al. recognized that both MCP-2 and MCP-1 recruit monocytes which are important in a variety of inflammatory conditions; thus the ordinary artisan at the time the invention was made would have been motivated to produce and screen multiple amino-terminal truncations of MCP-2 in order to identify an antagonist of MCP-2 that could be substituted or combined with antagonists of MCP-1, as exemplified by Rollins et al., to better inhibit monocyte recruitment in those inflammatory conditions. Furthermore, if the Rollins et al patent taught all the limitations of the instant claims, this rejection would be a 35 U.S.C. § 102(b) rejection rather than a 35 U.S.C. § 103 rejection.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicants arguments will be more convincing if the pending claims are amended to recite "an isolated amino-terminally truncated MCP-2 polypeptide consisting of residues....of SEQ ID NO:2".

#### **Conclusion**

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Prema Mertz*  
Prema Mertz Ph.D.  
Primary Examiner  
Art Unit 1646  
July 8, 2004